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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re PURDUE PHARMA L.P., *et al.*, Debtors.[1]	Chapter 11 Case No. 19-23649 (RDD) (Jointly Administered)

THE NON-CONSENTING STATES' STATEMENT WITH RESPECT TO PURDUE'S MOTION FOR AUTHORIZATION TO ENTER INTO DEVELOPMENT AGREEMENT

To the Honorable Robert D. Drain, United States Bankruptcy Judge:

Twenty-four States and the District of Columbia (the "States")[2] respectfully express their serious concerns regarding Purdue's motion for authorization to enter into a Development Agreement [Docket. No. 826] (the "Motion"). Although the States firmly agree that effective and efficient opioid rescue medicines are important, the Development Agreement is a highly

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

[2] California, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Idaho, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Hampshire, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, and Wisconsin.

speculative use of Purdue's resources that ultimately may not produce a public benefit and should not be seen as a blueprint for Purdue's future conduct and operations. Moreover, given Purdue's past conduct, Purdue likely is not an appropriate company to provide overdose-rescue medicines.

The Motion is an extension of a long line of efforts Purdue has considered to link the overdose *and* addiction business.[3] In 2014, Purdue considered Project Tango – a scheme to sell addiction treatment because "Pain treatment and addiction are naturally linked." Idaho Compl. ¶ 139. The business pitch read: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction." Colo. Compl. ¶ 393. In 2016, Purdue considered selling the overdose antidote nalaxone, because it is a "complementary" product to Purdue opioids and "could provide $24M in net sales to Purdue." N.J. Compl. ¶ 372. To date, Purdue has had limited success in the opioid rescue field.

Although Nalmefene, itself, has yet to be determined safe and effective and may not ultimately prove a successful reversal drug,[4] at least two other companies in the United States are developing nalmefene-based treatments, and nalmefene-based products are already on the market

[3] Purdue has repeatedly used the drug development process to serve its own ends while suggesting publicly that it intends to benefit the public health. It did so most notably by developing a so-called "abuse deterrent reformulation" of OxyContin to maintain government-sanctioned exclusivity and prevent the development of generic competition.

[4] *See* Stephens, Everett, M.D., *Opioid Toxicity Medication | Medication Summary. Medscape.* ("Nalmefene (Revex) and naltrexone are newer opioid antagonists that have longer half-lives than naloxone (4-8 h and 8-12 h vs 1 h). The routine use of a long-acting antagonist in the patient who is unconscious for unknown reasons is not recommended. In addition, the fear of precipitating prolonged opioid withdrawal likely prevents the widespread use of these antagonists for emergency reversal of opiate intoxication. In theory, nalmefene might be useful for persons with opiate addiction who accidentally overdose on heroin but refuse to stay for continued observation after an initial reversal dose of naloxone. However, this practice can be fatal to the patient who is discharged and then uses an excessive dose of opioids in order to counteract the withdrawal symptoms caused by the nalmefene. The routine use of this agent is not recommended."), *available at*: https://emedicine.medscape.com/article/815784-medication (last visited Feb. 19, 2020).

in Europe.[5] Considering that the original manufacturer of nalmefene in the United States discontinued the drug in May 21, 2008 for "business reasons,"[6] to the extent that there is a need for a nalfemene-based treatment, there is no reason to suggest that such a need cannot be addressed by other companies. Accordingly, Purdue developing a specialized delivery system for the drug may be of limited benefit in the real world.

Overdose reversal is a responsibility that should be entrusted to healthy companies that have not engaged in past deceptive marketing and other misconduct related to opioids. Purdue warns that, if the Court does not quickly grant the Motion, there is a "material risk" that its proposed business partner will work with someone else. Docket No. 824 at ¶ 12. But other companies may be better situated to develop the drug and its delivery system. The known facts and unresolved questions about Purdue's past misconduct may pose too many obstacles to Purdue's viability and suitability to be the company developing and marketing any overdose reversal drug.

CONCLUSION

Under these circumstances, the States file this Statement to make clear that the absence of objection at this time does not reflect an endorsement of (a) the Debtors' entry into the Development Agreement or (b) any public health initiatives. This Statement, however, should be

[5] Opiant Pharmaceuticals is developing an intranasal formulation of nalmefene and intends to file a new drug application with the FDA in 2020. *See OPNT003 Nalmefene Nasal Spray*, *available at*: https://www.opiant.com/products-pipeline/pipeline/opnt003-nalmefene-nasal-spray/ (last visited Feb. 19, 2020). In addition, Emergent BioSolutions Inc. is developing a sustained-release nalmefene formulation for the treatment of addiction in opioid use disorder. Press Release, *Emergent BioSolutions Receives NIH Research Grant to Further Develop AP007, Its Development Stage Sustained-Release Nalmefene Treatment for Opioid Use Disorder*, Sept. 17, 2019, *available at*: https://www.globenewswire.com/news-release/2019/09/27/1921743/0/en/Emergent-BioSolutions-Receives-NIH-Research-Grant-to-Further-Develop-AP007-Its-Development-Stage-Sustained-Release-Nalmefene-Treatment-for-Opioid-Use-Disorder.html (last visited Feb. 19, 2020).

[6] FDA, Determination That REVEX (Nalmefene Hydrochloride Injection), 0.1 Milligram Base/Milliliter and 1.0 Milligram Base/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 82 FR 51282, *available at*: https://www.federalregister.gov/documents/2017/11/03/2017-23952/determination-that-revex-nalmefene-hydrochloride-injection-01-milligram-basemilliliter-and-10 (last visited Feb. 19, 2020).

read as the States insisting that the Debtors carefully and rigorously monitor this project and exercise any offramps as soon as any of their assumptions about the project prove incorrect; and reserving their right to return to Court with respect to this Development Agreement should future circumstances require.

Dated: February 20, 2020

Respectfully submitted,

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By: */s/ Andrew M. Troop*

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CERTIFICATE OF SERVICE

I, Andrew M. Troop, hereby certify that, on February 20, 2020, I caused true and correct copies of the foregoing document to be served (i) by the Court's Case Management/Electronic Case File (CM/ECF) System to all parties who are deemed to have consented to electronic service; and (ii) by email upon the parties set forth in the Master Service List maintained by the Debtors in respect of these chapter 11 cases.

In addition, on February 20, 2020, I caused true and correct copies of the document to be served on the following:

Attn: Paul K. Schwartzberg
Office of the United States Trustee
Southern District of New York
201 Varick Street, Suite 1006
New York, NY 10014
Via Overnight Delivery Mail

/s/ *Andrew M. Troop*
Andrew M. Troop